UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re: BAYCOL PRODUCTS LITIGATION MDL No. 1431

This Document Relates to:

United States ex rel. Simpson,

MEMORANDUM OPINION AND ORDER

Relator, Case No. 08-5758 (MJD/SER)

v.

Bayer Healthcare d/b/a Bayer Healthcare Pharmaceuticals; Bayer Pharmaceuticals Corp.; Bayer Corporation; and Bayer A.G.,

Defendants.

Asher Alavi, Kessler Topaz Meltzer & Check LLP, Counsel for Relator Laurie Simpson.

Philip S. Beck and Adam Hoeflich, Bartlit Beck Herman Palenchar & Scott LLP, Ryan C. Morris and Kristin Graham Koehler, Sidley Austin LLP and John Marti, Alex P. Hontos and Caitlin L.D. Hull, Dorsey & Whitney LLP, Counsel for Defendants.

This matter is before the Court on Defendants Bayer Healthcare d/b/a Bayer Healthcare Pharmaceuticals, Bayer Pharmaceuticals Corp., Bayer Corporation and Bayer A.G.'s (collectively "Bayer") motion to dismiss the Second Amended

Complaint ("SAC") pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). [Doc. No. 156]

I. Background

A. Allegations in the Complaint and First Amended Complaint

Relator Laurie Simpson filed this action in the United States District Court, District of New Jersey on October 5, 2006 on behalf of the United States of America, eleven states and the District of Columbia, alleging claims under the False Claims Act, 31 U.S.C. § 3729 et seq. (the "FCA") and various state false claim act statutes concerning the statin drug Baycol, also known as cerivistatin. The matter was thereafter transferred to this District by the Judicial Panel on Multidistrict Litigation ("JPML") in October 2008.

In January 2009, Relator filed an Amended Complaint in which she alleged that Bayer's marketing and sale of the drug Baycol violated the FCA, and that the false and fraudulent statements at issue involved payments made by federally-funded programs and by state-funded programs including Medicare, Medicaid, the Federal Employees Health Benefits Program ("FEHBP"), TRICARE/CHAMPUS for prescription drugs, and the Department of Defense ("DoD"). (Amended Complaint ¶ 1.)

By Memorandum Opinion and Order dated September 30, 2010, the Court granted Bayer's motion to dismiss. The Court dismissed certain claims with prejudice, and the remaining claims were dismissed without prejudice pursuant to Rule 9(b) of the Federal Rules of Civil Procedure, for failing to plead fraud with particularity. Relator was given leave to amend her complaint. Further, the Court noted that any claim arising prior to October 5, 2000 would be time-barred. On November 23, 2010, Relator filed the SAC.

B. Allegations in the Second Amended Complaint

Relator alleges that among other government-funded agencies, the DoD had a contract with Bayer for Baycol, and paid Bayer millions of dollars for Baycol during the relevant time period. (SAC ¶ 5.) Relator also alleges that through illegal kickbacks and misbranding, Bayer caused false claims to be filed, which claims would not have been paid had the full truth been known. (Id. ¶ 6.) She further alleges that Bayer engaged in deceptive and misleading conduct in order to increase the overall market share of Baycol by inducing physicians to prescribe Baycol who otherwise may not have done so. (Id.)

Relator alleges she was hired by Bayer as a Senior Market Research Analyst in April 1998 and was assigned to the Baycol marketing team. (Id. ¶ 7.) In that

position, she participated in the development and refinement of marketing messages, assessed product perceptions of Baycol and its competitors, evaluated communications to physicians and the public, conducted product pricing studies, participated in assessing sample requirements and attended copy approval meetings as well as the Baycol product team and Joint Marketing team meetings devoted to Baycol promotion. (Id. ¶ 8.) Relator further alleges that she routinely translated clinical trial information into potential marketing material, and she routinely participated in discussions with other team members about the design and status of Baycol clinical trials. (Id. ¶¶ 9 and 10.) In 1998, Relator began to conduct competitive intelligence activities, and developed and maintained a clinical trial database, as well as provided input to clinical trial designs. (Id. ¶¶ 11 and 13.) Because of her position and duties, Relator asserts that she is uniquely positioned to detail Bayer's knowledge concerning the risks attendant with Baycol, when those risks became known and Bayer's steps to conceal those risks. (Id. ¶ 14.)

Relator alleges that Bayer engaged in improper and unlawful marketing strategies, including kickbacks, to increase market shares, marketed Baycol with defective and inadequate warnings to downplay the risks, and intentionally

misrepresented, concealed or omitted facts and refrained from taking steps to learn facts about Baycol in connection with its communications to the public, government representatives and to physicians. (Id. ¶¶ 15-16.) Relator further alleges that if government representatives had known of the foregoing deceptive, misleading and improper conduct, they would not have contracted to purchase Baycol. (Id. ¶ 17.)

The SAC also includes allegations that the DoD entered into the following contracts with Bayer concerning Baycol - a January 2001 renewal contract and a February 2001 Blanket Purchase Agreement ("BPA"). Relator alleges that Bayer, in response to specific inquiries by personnel from the DoD, misrepresented the efficacy of Baycol and the known risks associated with Baycol in certain communications sent in November and December 1999 and January 2000. (SAC ¶¶ 105-112, 116-120.)

Relator further alleges that Bayer was involved in, and arranged for, studies to be conducted by Pacificare, and that such studies were fraudulent and misrepresented the safety of Baycol. (Id. ¶¶ 125-138.)

By Order dated July 18, 2012, this Court granted Bayer's motion to dismiss the SAC, and dismissed all claims with prejudice. The Court found that dismissal

was appropriate as Relator again failed to comply with Fed. R. Civ. P. 9(b) by not including allegations linking the government's decision to purchase Baycol to specific fraudulent representations, and that particular claims submitted were fraudulent. (Doc. No. 71 at 15-16.)

On appeal, the Eighth Circuit affirmed this Court's dismissal of Relator's claims relating to federal health insurance reimbursements, but reversed as to Relator's claim that the DoD was fraudulently induced to enter into the 2001 renewal contract and the BPA. In re Baycol Prod. Litig., 732 F.3d 869, 876-77 (8th Cir. 2013) ("Baycol I"). The court found that Relator had sufficiently alleged a claim of fraudulent inducement under the FCA by alleging that Bayer fraudulently induced the DoD to agree to a contract extension in January 2001 and to enter into the BPA for a higher dosage for Baycol in February 2001 by misrepresenting the risks associated with Baycol in particular communications sent in November and December 1999 and January 2000. Baycol I, 732 F.3d at 876-77. The case was remanded for further proceedings.

Following remand, Bayer again moved to dismiss the SAC, arguing that to the extent Relator asserts a claim for fraudulent inducement under the FCA, such claim must be dismissed for lack of subject matter jurisdiction as Relator is not

the original source of the publicly disclosed allegations contained in the SAC with respect to this claim. Bayer further argued that the DoD allegations are time-barred because they do not share a common core of operative facts with those in the original complaint, and thus do not relate back.

By Order dated March 31, 2015, the Court granted the motion to dismiss on the grounds that Relator had failed to demonstrate that she was an original source of the allegations forming the basis of the fraudulent inducement claim involving the DoD. (Doc. No. 130.) The Court did not address Bayer's argument that the claim is time-barred.

On appeal, the Eighth Circuit reversed and remanded the matter to this Court to determine whether Relator had direct and independent knowledge of the "true state of the facts" concerning the fraudulent inducement claim; that Bayer possessed evidence which showed that Baycol was not as efficacious as represented and caused increased risk of rhabdomyolysis. In re Baycol Prod. Litig., 870 F.3d 960, 962 (8th Cir. 2017) ("Baycol II"). Further, the court held that whether or not Relator's claim is barred by the statute of limitations should first be determined by the district court. Id.

II. The False Claim Act

The FCA makes it unlawful to knowingly present or cause to be presented a false or fraudulent claim for payment to the government. 31 U.S.C. § 3729(a)(1)(A). Although the FCA focuses on false claims submitted to the government for payment, courts have recognized a fraudulent inducement theory to establish liability for each claim submitted under a contract that was procured by fraud, even if the claim itself was not fraudulent. United States ex rel. Marcus v. Hess, 317 U.S. 537 (1943).

To prevail on a claim of fraudulent inducement, "a plaintiff must show that (1) there was a knowingly false or fraudulent statement; (2) that the statement was material; and (3) that it caused the government to pay out money or to forfeit moneys due (i.e., a "claim")." United States ex rel. Thomas v. Siemens AG, 593 F. App'x 139, 143 (3d Cir. Nov. 25, 2014) (citing United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 242 (3d Cir. 2004) and Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 785 (4th Cir. 1999)).

A. Subject Matter Jurisdiction

Bayer moves to dismiss this claim, arguing that this Court does not have subject matter jurisdiction over the fraudulent inducement claim because Relator

cannot demonstrate that the jurisdictional requirements of 31 U.S.C. § 3730(e)(4) have been met.

When determining whether it has subject matter jurisdiction over an action, the Court must keep in mind that "no presumptive truthfulness attaches to the plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." Osborn v. United States, 918 F.2d 724, 730 (8th Cir. 1990) (quoting Mortensen v. First Fed. Sav. & Loan Ass'n, 549 F.2d 884, 891 (3d Cir. 1977)). The plaintiff bears the burden of proving that jurisdiction exists. Id. "Once evidence is submitted, the district court must decide the jurisdictional issue, not simply rule that there is or is not enough evidence to have a trial on the issue." Id.

When addressing a factual attack as to subject matter jurisdiction over a claim, the Court is free to consider matters outside of the pleadings. See Osborn, 918 F.2d at 729, n.6; Parsons v. United States Air Force, 221 F.3d 1343 (8th Cir. 2000) (Table) (holding that where a defendant asserts a factual challenge to jurisdiction, the district court is free to weigh the evidence and determine the existence of its power to hear the case and no presumptive truthfulness attaches to allegations in the complaint).

1. Section 3730(e)(4) Requirements

The FCA specifically authorizes a private party to bring an action on behalf of the government "to promote private citizen involvement in exposing fraud against the government, while at the same time prevent parasitic suits by opportunistic late-comers who add nothing to the exposure of the fraud." United States ex. rel. Rabushka v. Crane Co., 40 F.3d 1509, 1511 (8th Cir. 1995). To achieve this balance, the FCA provides that:

> (4)(A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

31 U.S.C. § 3730(e)(4) (1986).

This Court previously found that Relator's claims are based on public information (Doc. No. 50 at 16), therefore she can only proceed if she demonstrates that she is an original source of the information on which the

allegations of fraudulent inducement are based.

2. Original Source

a. Direct and Independent Knowledge

Relator is deemed to be an original source if she has first hand knowledge of the information on which the allegations are based. Rockwell Intern. Corp. v. United States, 549 U.S. 457, 470 (2007). By contrast, if Relator "obtains secondhand information from an individual who has direct knowledge of the alleged fraud" she is not considered an original source under the FCA. United States ex rel. Barth v. Ridgedale Elec. Inc., 44 F.3d 699, 703 (8th Cir. 1995). "Accordingly, 'collateral research and investigation . . . [do] not establish 'direct and independent knowledge of the information on which the allegations are based within the meaning of § 3730(e)(4)(B).'" Id. (quoting United States ex rel. Kreindler & Kreindler v. United Tech. Corp., 985 F.2d 1148, 1159 (2d Cir. 1993)).

Direct knowledge does not require knowledge of all elements of a cause of action, however. Mn. Assoc. of Nurse Anesthetists v. Allina Health Sys. Corp., 276 F.3d 1032, 1050 (8th Cir. 2002). "If the relator has direct knowledge of the true state of the facts, it can be an original source even though its knowledge of the misrepresentation is not first-hand." Id. As applied in this case, the Eighth

Circuit held that Relator does not have to "have direct and independent knowledge of Bayer's allegedly false communications to the Department of Defense." Baycol II, 870 F.3d at 962. Instead, as long as she can demonstrate direct knowledge of the true state of the facts - "that Bayer allegedly possessed evidence to know that Baycol was not as efficacious as represented and caused increased risks of rhabdomyolysis" - "she can be an original source even though her 'knowledge of the misrepresentation is not first-hand.'" Id.

Bayer argues that because Relator has disclaimed direct and independent knowledge of the alleged misrepresentations made to the DoD, she must demonstrate direct and independent knowledge of why the representations to the DoD were knowingly false when made, and she has failed to meet that burden.

Relator claims she has met the burden. (See SAC ¶¶ 107-08, 112, 123, 157-60, 168, Supp. Simpson Decl. ¶¶ 7, 10) For example, Relator alleges that she participated in Baycol Project Team meetings and other discussions in which concerns about Baycol causing rhabdomyolysis were discussed. (SAC ¶ 121.) In early 1999, in response to increased cases of rhabdomyolysis, Relator agreed to obtain adverse event information from the FDA through a FOIA request. (Id. ¶ 157.) At that time, Baycol 0.3 mg was the highest dose on the market. (Id.) Once

she received information on the adverse events reports, she drafted a summary and circulated it to product management. (Id.) In this summary, Relator wrote "there was very likely a material difference in adverse event rates between Baycol and other statins, and that further investigation should be pursued." (Id.) Relator was later directed to remove this conclusion from her report, in case of litigation. (Id.)

In October 1999, Relator issued a second FOIA request to the FDA to obtain additional data on statin adverse events. After receiving the response to this request, Relator prepared another summary, which she alleges made an even more compelling case that Baycol differed from other statins in potential health risks. (Id. at ¶ 168.) Relator passed the information to Bayer's Drug Safety Department for further analysis. (Id.)

Despite the information coming in as to adverse events, Bayer continued to downplay this information and market Baycol as comparable in safety to other statins. (Id. ¶¶ 123, 143-44, 173, 197, 203.)

Relator further alleges that in September 1998, Dr. Ebsworth, Bayer's CEO, directed the marketing team to overstate Baycol efficacy, by marketing it as comparable in efficacy to Lipitor, even though current clinical data did not

support that claim. (SAC ¶¶ 146-47 & n.5.) Relator also includes allegations concerning her participation in discussions regarding Baycol clinical studies, and that from these discussions and through her review of the DoD studies where patients were switched from another statin to Baycol, Relator observed that Bayer misleadingly attributed National Cholesterol Education Program goal attainment to Baycol efficacy rather than to temporarily increased compliance that such switches generate. (Id. ¶ 233.)

Relator asserts her knowledge extends to specific instances of misstatements. For example, in the fall of 1999, the DoD raised concerns about relative incidence of rhabdomyolysis with Baycol compared with other statins. In response, Casimir Zygmunt, a Clinical Specialist from Bayer Clinical Communications, wrote that there was no evidence to suggest that Baycol causes more rhabdomyolysis. (SAC ¶ 105.) Relator claims that this was a false statement, because Bayer and Zygmunt in particular, had the adverse event analysis Relator prepared. In support, Relator cites to paragraphs 107, 157-58 in the SAC and paragraph 10 in Relator's Supplemental Declaration and the attached emails.

While a review of these citations to the record do not conclusively show that

Zygmunt received Relator's report with the conclusion that suggested a higher rate of rhabdomyolysis with Baycol when he wrote to the DoD in November 1999, Relator argues this has no bearing on her knowledge of the true state of the facts, because Zygmunt wrote there was no evidence to **suggest** Baycol caused more rhabdomyolysis, not that there was no evidence **concluding** that it did. Further, while Bayer had not reached a formal conclusion on the adverse event rates at that time, the fact that Relator was directed to remove her conclusion that there was likely a material difference in adverse events rates between Baycol and other statins, corroborates Bayer's knowledge of information contradicting false representations.

With regard to the December 1999 statement to the DoD that there was insufficient data upon which to base a dose-response relationship, Relator asserts that in late 1998 and early 1999, she participated in discussions regarding the high rate of adverse events in an ongoing clinical trial for 1.6 mg dose and learned of Bayer's decision to conceal the study from the public and the DoD. (Supp. Decl. ¶ 17.) By spring 2000, she knew that it was internally recognized by Bayer that higher doses were associated with greater safety concerns. (Id. ¶¶ 11-12.)

Relator further claims that the facts which reveal Bayer's December 1999

statement to be knowingly false are not limited to issues discussed at one meeting. Nor is the true state of facts inquiry dependent on whether Relator knew that Bayer possessed evidence of a dose-response relationship with the 0.8 mg dose of Baycol. Relator has alleged that Bayer falsely represented that there was insufficient data to support a dose-response relationship with Baycol during a time when it knew there was evidence of such a relationship; whether it was 0.8 or 1.6 mg is beside the point. Further, by citing to paragraph 190, in which she alleges she was not aware of a reason not to **start** patients at 0.8 mg until late 2000, Bayer misses the point. That paragraph does not state Relator lacked awareness of a dose-response relationship with Baycol. In fact, the paragraphs cited by Bayer support that Relator was personally aware that Bayer was trying to downplay and conceal from the DoD the dangers of using 0.8 mg as a starting dosage before the DoD entered into the BPA for that dosage in February 2001.

Finally, Relator argues that the Court has already found that she is an original source of allegations that are central to her fraudulent inducement claim - that Bayer concealed and misrepresented the risks of Baycol, and engaged in fraudulent marketing of Baycol. The new allegations concerning the fraudulent inducement of the contracts with the DoD are simply additional details that

provide further support to the core allegations.

Bayer has put forth some valid arguments. For example, the Court agrees that Relator cannot rely on allegations based on "information and belief" to demonstrate direct and independent knowledge, and that Relator cannot leverage allegations concerning general marketing knowledge into first hand knowledge concerning specific communications. However, for purposes of determining subject matter jurisdiction, the Court finds that Relator has alleged sufficient facts to show she has direct and independent knowledge that Bayer possessed evidence showing that Baycol was not as efficacious as represented and caused increased risks of rhabdomyolysis.

b. Whether Relator Informed the Government of Claims Prior to Filing Suit

In addition to demonstrating direct and independent knowledge of the allegations supporting a claim under the FCA, a relator must also demonstrate that he/she provided such information to the government before filing suit. Mn. Assoc. of Nurse Anesthetists, 276 F.3d at 1042.

Bayer argues that even if Relator had direct and independent knowledge of

the information on which the new allegations are based, she still cannot qualify as an original source if she did not voluntarily provide the information to the government prior to filing suit. Bayer argues that Relator has provided no basis upon which the Court can find that she gave the government any of the information underlying the new allegations of fraudulent inducement.

Subsequent to the filing of the SAC, Relator submitted a declaration in which she stated: "I first approached the Federal Government in early 2005, disclosing information upon which this action is based. Subsequently, I commenced this action in October 2006. Additionally, the information I disclosed to the Federal Government included information relating to the Pacificare studies and to the Department of Defense." (Doc. No. 61 ¶ 2.) Relator's counsel, Robert Sadowski, also filed a declaration in which he states that he provided the government a copy of the SAC. (Doc. No. 62 ¶ 2.) He does not state in the declaration, however, whether the copy was provided prior to its filing.

As discussed below, the Court finds the allegations of fraudulent inducement involving the renewal of the DoD contracts in 2001 relate back to the allegations contained in the original complaint. Accordingly, the Court finds that Relator has demonstrated that she voluntarily provided the information

underlying her claims to the government prior to filing the SAC.

B. Statute of Limitations

FCA claims are subject to a six year statute of limitations. 31 U.S.C. § 3731(b)(1). This Court previously held that "[t]o the extent any of Relator's claims are based on false claims submitted prior to October 5, 2000, six years from the date her complaint was filed, such claims are time-barred." (Doc. No. 50 at 30.)

1. Relation Back

Bayer argues that the allegations underlying the fraudulent inducement claims, first asserted in the SAC, are barred by the six year statute of limitations as these allegations do not arise from the same "conduct, transaction or occurrence" set out in the first complaint and therefore do not relate back to the filing of that complaint.

Pursuant to Fed. R. Civ. P. 15(c)(1)(B), "an amendment to a pleading relates back to the date of the original pleading when . . . the amendment asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out - or attempted to be set out - in the original pleading. The basic inquiry is whether the amended complaint is related to the general fact situation alleged in the original

pleading." Alpern v. UtiliCorp United, Inc., 84 F.3d 1525, 1543 (8th Cir. 1996). In addition, the purpose of Rule 15 is to permit cases to be decided on the merits, therefore it should be construed liberally. Id.

At the same time, an important consideration in determining whether a new claim in an amended complaint relates back is whether the original complaint provides sufficient notice to the defendant of the factual basis for that new claim, and whether the passage of time would prejudice the opposing party. Fuller v. Marx, 724 F.2d 717, 720 (8th Cir. 1984).

It is Bayer's position that it did not have sufficient notice of the fraudulent inducement claim, therefore the Court should find that claim does not relate back. Popp Telecom, Inc. v. Am. Sharecom, Inc., 361 F.3d 482, 490 n.8 (8th Cir. 2004) (noting that because new facts alleged in amended complaint did not provide sufficient notice of claim, relation back was not warranted). Bayer further argues that the passage of nearly twenty years will unduly prejudice its ability to present a defense, as the claim may rest on whether witnesses made certain statements, whether they knew such statements were false when made and whether DoD witnesses relied on those statements in making the decision to renew the contracts in 2001.

The Court finds that the new allegations supporting the fraudulent inducement claim arise out of the same conduct, transaction or occurrence that is set out in the original complaint. The original complaint included allegations that Bayer had a contract with the DoD, that Bayer fraudulently misrepresented the efficacy and safety risks of Baycol, and that had the government known the truth, it would not have paid any monies under the DoD contract. The SAC includes more detailed allegations, such as describing the contractual relationship with the DoD, that Bayer misrepresented Baycol's safety and efficacy to representatives of the government and alleged that the government would not have contracted for or purchased Baycol had it known about Bayer's misrepresentations.

Because the fraudulent inducement claim arises out of the same conduct, transaction or occurrence set out in the original complaint, the Court finds that Bayer was not deprived of fair notice of such claim.

Finally, the Court recognizes that nearly twenty years have passed since the allegedly fraudulent statements were made. However, it appears that the fraudulent inducement claim is based largely on documents, such as letters and emails, and may be proved or disproved through documents. Accordingly, at this time, the Court will deny the motion to dismiss - based on the statute of

limitations - without prejudice. Following the completion of discovery, Bayer may renew this argument in a motion for summary judgment.

Accordingly,

IT IS HEREBY ORDERED that Bayer's Motion to Dismiss [Doc. No. 156] is **DENIED** as set forth in the above Memorandum Opinion.

Date: October 16, 2018

s/ Michael J. Davis
Michael J. Davis
United States District Court